APR 19 2012

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This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

DATE:	April 11, 2012
APPLICANT:	NeoMed, Inc. 100 Londonderry Ct Suite 112 Woodstock, GA 30188 Tony Lair, President Tel: 770-516-2225 email: lair1@concentric.net
OFFICIAL CORRESPONDENT:	Penny Northcutt, RAC, CQA Regulatory Consultant for NeoMed, Inc. REGSolutions, LLC Tel: 678-428-6978 Fax: 678-513-0937 email: pennynorthcutt@theregsolutions.com
TRADE NAME:	NeoMed Gastrointestinal Tube and Accessories
CLASSIFICATION NAME:	Tubes, Gastrointestinal (and accessories)
DEVICE CLASSIFICATION AND PRODUCT CODE:	Class II per 21 CFR §876.5980 Gastroenterology/Urology Product Code: KNT
PREDICATE DEVICE NAME:	Vygon Nutrisafe 2, K060944 Kendall Argyle PVC Feeding Tube, K820441 (Sherwood)

SUBSTANTIAL EQUIVALENCE:

The NeoMed Gastrointestinal Tube and Accessories is substantially equivalent to the legally marketed Vygon Nutrisafe 2 (K060944) and Kendall Argyle PVC Feeding Tube (K820441). In addition, the NeoMed PVC feeding tube device design is the same as previously cleared NeoMed Silicone (K072881) and Polyurethane (K082238) Feeding Tubes.

TECNOLOGICAL CHARACTERISTICS:

The NeoMed Gastrointestinal Tube and Accessories have similar technological characteristics when compared to the predicate devices. They have similar indications for use, materials, product design, and principles of operation. Bench testing has demonstrated that the NeoMed Gastrointestinal Tube and Accessories is functionally equivalent to the proposed predicate feeding tubes. Any minor differences do not affect safety or effectiveness of the NeoMed Gastrointestinal Tube and Accessories.

DESCRIPTION OF THE DEVICE:

The NeoMed Gastrointestinal Tube and Accessories is a PVC single lumen catheter that is used to deliver liquid nutritional media. This NeoMed PVC feeding tube is designed to connect with other NeoMed accessories such as the NeoMed Extension tubing under FDA clearance K100288 and NeoMed oral syringe under FDA clearance K092908.

The device consists of the following main components: a feeding tube single lumen catheter and a one-piece molded enteral only connector hub with integral tethered connection closure plug. The catheter tubing has an orange radiopaque stripe of barium sulfate embedded in the tubing wall which can be visualized on x-ray, for exact placement of the tip. The tip is closed. The single lumen catheter tubing has side holes for better flow and to provide multiple openings for aspiration.

INTENDED USE/INDICATIONS FOR USE:

The NeoMed Gastrointestinal Tube and Accessories is intended for short-term use < 30 days in neonatal and pediatric patients to provide nutrition via nasal or oral gastric placement.

PERFORMANCE DATA:

The NeoMed Gastrointestinal Tube and Accessories materials have a long history of use in feeding tube manufacturing and are biocompatible and have been evaluated in accordance with ISO 10993-1: Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing and these tests pass.

Design verification functional test results including tensile strength, dimensions, non-interconnectability, and priming volume demonstrate that the NeoMed Gastrointestinal Tube and Accessories performs its intended use and is substantially equivalent to the predicate devices by Kendall and Vygon.

CONCLUSION:

Based on the performance testing, it can be concluded that the NeoMed Gastrointestinal Tube and Accessories is equivalent to the Vygon Nutrisafe 2 (K060944) and Kendall Argyle PVC Feeding Tube (K820441) predicts with respect to intended use, materials, design, and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NeoMed, Inc.
% Ms. Penny Northcutt
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APR 19 2012

Re: K120182
Trade/Device Name: NeoMed Gastrointestinal Tube and Accessories
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: January 19, 2012
Received: January 20, 2012

Dear Ms. Northcutt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120182

Device Name: **NeoMed Gastrointestinal Tube and Accessories**

Indications For Use:

This product is intended for short-term use (< 30 days) in neonatal and pediatric patients to provide nutrition via nasal or oral gastric placement.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K120182